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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/869,386 06/05/97 SASTRY

J

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EXAMINER

SMITH, L

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

08/13/98

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/869,386

Applicant(s)

Sastry et al

Examiner

Lynette R. F. Smith

Group Art Unit

1648



☒ Responsive to communication(s) filed on May 29, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 29-47 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 29-47 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1648

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The examiner acknowledges receipt of the declaration of Dr. Sastry and manuscript of Dr. Nehete et al.

4. It appears that the substitute specification was not attached to the amendment, therefore the request for filing a substitute specification is maintained. Applicant is directed to MPEP 608.01(q) and 37 CFR 1.125 concerning the submission of a substitute specification and marked-up copy. Additionally, it should be noted that there were several hand written corrections to the specification which had no accompanying signature. Applicant is required to submit a supplemental oath or declaration in accordance with 37 CFR 1.67(c), 1.121, 1.123 or 1.125.

5. The examiner acknowledges the amendment to the claims, the cancellation of claims 1-28 and 48. Claims pending are claims 29-47. In view of the amendments to the claims, all rejections of record are being withdrawn.

#### **New Grounds of Rejection**

6. The disclosure is objected to because of the following informalities: the specification contains a section entitled brief description of the drawings. However, there were no drawings submitted. It appears that the figures may have become separated from the file. Applicant is

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respectfully requested to supply additional copies of the drawings. It should be noted that the file wrapper indicated that no drawings were filed with the application (see enclosed copy of the face of the file). Additionally, the amendment filed 10/2/97 requested deletion of the sequence listing beginning on page 79 and insertion of an amended sequence listing. The amended sequence listing indicates on the first page that there are 46 sequences. However subsequent pages only contain 45 sequences. Please correct this discrepancy. Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 29-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language of the claims is not as precise as the subject matter permits such that one may reasonably know the metes and bounds of the claims. The claims are indefinite in the recitation of "directly inhibiting HIV entry into a cell" because it is unclear from the specification what applicant intends. Clarification is required in order to overcome this rejection.

8. Claims 29-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended claims are drawn to a method for directly inhibiting HIV entry into a cell comprising contacting the cell with the claimed peptides. This appears to be new matter and appears to lack support in the specification. As has been pointed out by applicant,

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page 14 of the original specification states that "HIV infection-inhibiting sequence" refers to a peptide sequence which prevents entry of the HIV virus into its target cell. It should be noted, however, that the specification does not state that the sequences directly inhibit HIV infection. Indeed the specification continues to define infection-inhibiting peptides to "particularly include peptides that comprise a sequence wherein antibodies against that sequence are capable of inhibiting HIV cellular infection." (See also pages 47-51). Similarly, page 17, lines 26-30 state that it is contemplated that "any sequence where anti-peptide antibodies against that sequence have been shown to inhibit viral entry into cells will be a suitable HIV infection-inhibiting peptide....". Additionally, the specification also appears to be directed to the generation of cytotoxic T cell responses (pages 32-36, 53-63). This would appear to be contradictory to the statements made in applicant's response filed under 37 CFR 1.111. While the examiner acknowledges the declaration submitted, the issue of new matter must be resolved. Applicant is required to point to where in the specification there is support for the invention as is now claimed or cancel the new matter.

9. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Lynette F. Smith, Art Unit 1648 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1648 FAX telephone number is (703)-305-4242. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX

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machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lynette F. Smith whose telephone number is (703) 308-3909.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, can be reached on (703) 308-0570.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SMITH/lfs  
August 5, 1998